



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request;

Information Collection Request Title: Data System for Organ Procurement and

Transplantation Network, OMB No. 0915-0157 - Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or by mail to the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Samantha Miller, the HRSA Information Collection Clearance Officer at (301) 443-9094.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information collection request title for reference.

Information Collection Request Title: Data System for Organ Procurement and Transplantation Network (OPTN), OMB No. 0915-0157 – Revision.

Abstract: Section 372 of the Public Health Service Act requires that the Secretary of HHS, by contract, provide for the establishment and operation of a private, non-profit entity the OPTN, which on behalf of HRSA, oversees the U.S. donation and transplantation system. The OPTN Board of Directors (BOD) determines what data must be collected to appropriately fulfill their responsibilities pursuant to their regulatory authority in 42 CFR 121.11 of the OPTN Final Rule. HRSA, on behalf of the OPTN BOD and in alignment with the Paperwork Reduction Act of 1995, submits OPTN BOD-approved data elements for collection to OMB for official federal approval.

Need and Proposed Use of the Information: HRSA and the OPTN BOD use data to develop transplant, donation, and allocation policies; to determine whether institutional members are complying with policy; to determine member-specific performance; to ensure patient safety, and to fulfill the requirements of the OPTN Final Rule. In addition, the regulatory authority in 42 CFR 121.11 of the OPTN Final Rule requires the OPTN data to be made available, consistent with applicable laws, for use by OPTN members, the Scientific Registry of Transplant Recipients, HHS, and members of the public for evaluation, research, patient information, and other important purposes.

This is a request to revise the current OPTN data collection which includes time-sensitive, life-critical data on transplant candidates and donors, the organ matching process, histocompatibility results, organ labeling and packaging, and pre- and post-transplantation data on recipients and donors. This revision also includes OPTN BOD-approved changes to the existing OMB data collection forms. The OPTN collects these specific data elements from transplant hospitals, organ procurement organizations, and histocompatibility laboratories. The OPTN uses this information to (1) facilitate organ placement and match donor organs with recipients, (2) monitor compliance of member organizations with federal laws and regulations

and with OPTN requirements, (3) review and report periodically to the public on the status of organ donation and transplantation in the United States, (4) provide data to researchers and government agencies to study the scientific and clinical status of organ transplantation, and (5) perform transplantation-related public health surveillance including the possible transmission of donor disease.

HRSA is requesting to make the following OPTN BOD-approved changes to improve the OPTN organ matching and allocation process and improve OPTN member compliance with OPTN requirements:

- (1) Adding data collection forms from the OPTN donor management and organ matching system to the existing OMB-approved information collection. The system allows an organ procurement organization to add donors, run the donor/potential transplant recipients matches, and place a donated organ(s) with a computer-matched potential transplant recipient. Transplant centers will access the system to view posted donor information to assist them with accepting decisions, along with other donor/potential transplant recipient functions such as entering offer responses and verifying organ offer refusals. The OPTN donor management and organ matching system is comprised of eight data collection forms: initial donor registration, organ procurement organization notification limit administration, potential transplant recipient, death notification registration, deceased donor death referral, donor hospital registration, donor organ disposition, and transplant center contact management.
- (2) The OPTN BOD-approved additional revisions to existing data collection forms to improve organ matching, allocation, and OPTN policy compliance.
- (3) Existing OPTN data collection forms that collect a single race and ethnicity variable will be revised to collect separate race and ethnicity variables, following the minimum standards for collecting and presenting data on race and ethnicity for all federal reporting found within *Revisions of Standards for the Classification of*

Federal Data on Race and Ethnicity, OMB Statistical Policy Directive No. 15 in *Federal Register*, 62 FR 58782 (Oct. 30, 1997). Improving data collection around race and ethnicity information of donors and candidates aligns with Executive Order 13985, which calls on agencies to advance equity through identifying and addressing barriers to equal opportunity that underserved communities may face due to government policies and programs.

Likely Respondents: Transplant programs, organ procurement organizations (OPO), and histocompatibility laboratories.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

The estimated total estimated burden hours for this collection increased by 213,662 hours from the currently approved ICR package. This increase is due to the addition of eight collection forms from the OPTN donor management and organ matching system to this data collection package, specifically the burden increase from the Potential Transplant Recipient form. While the data fields collected on the Potential Transplant Recipient form are limited, the volume of organ offer responses is significant due to the large number of potential transplant recipients shown on the organ match run results. The organ match run results produce thousands of potential transplant recipients that require responses from OPOs and transplant hospitals. This volume of candidates significantly impacts the total burden hours for this form.

Total Estimated Annualized Burden Hours:

Form Name	Number of Respondents*	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Deceased Donor Registration	57	243.560	13,883	1.09	15,132
Living Donor Registration	216	28.106	6,071	2.19	13,295
Living Donor Follow-up	216	90.550	19,559	1.52	29,730
Donor Histocompatibility	141	149.184	21,035	0.20	4,207
Recipient Histocompatibility	141	264.950	37,358	0.40	14,943
Heart Transplant Candidate Registration	145	34.586	5,015	0.90	4,514
Heart Transplant Recipient Registration	145	26.324	3,817	1.40	5,344
Heart Transplant Recipient Follow-Up (6 Months)	145	24.400	3,538	0.40	1,415
Heart Transplant Recipient Follow-Up (1-5 Years)	145	104.140	15,100	0.90	13,590
Heart Transplant Recipient Follow-Up (Post 5 Year)	145	171.100	24,810	0.50	12,405
Heart Post-Transplant Malignancy Form	145	13.170	1,910	0.90	1,719
Lung Transplant Candidate Registration	72	42.970	3,094	0.90	2,785
Lung Transplant Recipient Registration	72	35.010	2,521	1.20	3,025
Lung Transplant Recipient Follow-Up (6 Months)	72	33.630	2,421	0.50	1,211
Lung Transplant Recipient Follow-Up (1-5 Years)	72	139.940	10,076	1.10	11,084
Lung Transplant Recipient Follow-Up (Post 5 Year)	72	136.280	9,812	0.60	5,887
Lung Post-Transplant Malignancy Form	72	22.630	1,629	0.40	652
Heart/Lung Transplant Candidate Registration	70	0.960	67	1.10	74
Heart/Lung Transplant Recipient Registration	70	0.640	45	1.30	59
Heart/Lung Transplant Recipient Follow-Up (6 Months)	70	0.600	42	0.80	34
Heart/Lung Transplant	70	2.100	147	1.10	162

Recipient Follow-Up (1-5 Years)					
Heart/Lung Transplant Recipient Follow-Up (Post 5 Year)	70	3.360	235	0.60	141
Heart/Lung Post-Transplant Malignancy Form	70	0.290	20	0.40	8
Liver Transplant Candidate Registration	143	96.920	13,860	0.80	11,088
Liver Transplant Recipient Registration	143	64.580	9,235	1.20	11,082
Liver Transplant Recipient Follow-Up (6 Month - 5 Year)	143	320.266	45,798	1.00	45,798
Liver Transplant Recipient Follow-Up (Post 5 Year)	143	384.320	54,958	0.50	27,479
Liver Recipient Explant Pathology Form	143	7.300	1,044	0.60	626
Liver Post-Transplant Malignancy	143	19.060	2,726	0.80	2,181
Intestine Transplant Candidate Registration	21	6.860	144	1.30	187
Intestine Transplant Recipient Registration	21	4.570	96	1.80	173
Intestine Transplant Recipient Follow-Up (6 Month - 5 Year)	21	20.050	421	1.50	632
Intestine Transplant Recipient Follow-Up (Post 5 Year)	21	40.190	844	0.40	338
Intestine Post-Transplant Malignancy Form	21	0.620	13	1.00	13
Kidney Transplant Candidate Registration	234	177.000	41,418	0.80	33,134
Kidney Transplant Recipient Registration	234	105.397	24,663	1.20	29,596
Kidney Transplant Recipient Follow-Up (6 Month - 5 Year)	234	517.124	121,007	0.90	108,906
Kidney Transplant Recipient Follow-Up (Post 5 Year)	234	525.103	122,874	0.50	61,437
Kidney Post-Transplant Malignancy Form	234	24.474	5,727	0.80	4,582
Pancreas Transplant Candidate Registration	120	2.650	318	0.60	191
Pancreas Transplant Recipient Registration	120	1.190	143	1.20	172
Pancreas Transplant Recipient Follow-Up (6 Month - 5 Year)	120	6.680	802	0.50	401
Pancreas Transplant	120	17.820	2138	0.50	1,069

Recipient Follow-Up (Post 5 Year)					
Pancreas Post-Transplant Malignancy Form	120	1.060	127	0.60	76
Kidney/Pancreas Transplant Candidate Registration	120	12.450	1,494	0.60	896
Kidney/Pancreas Transplant Recipient Registration	120	6.840	821	1.20	985
Kidney/Pancreas Transplant Recipient Follow-Up (6 Month - 5 Year)	120	39.440	4,733	0.50	2,367
Kidney/Pancreas Transplant Recipient Follow-Up (Post 5 Year)	120	69.410	8,329	0.60	4,997
Kidney/Pancreas Post-Transplant Malignancy Form	120	2.490	299	0.40	120
VCA Transplant Candidate Registration	21	0.330	7	0.40	3
VCA Transplant Recipient Registration	21	0.190	4	1.36	5
VCA Transplant Recipient Follow Up	21	1.000	21	1.31	28
Organ Labeling and Packaging	57	247.720	14,120	0.18	2,542
Organ Tracking and Validating	308	19.487	6,002	0.08	480
Kidney Paired Donation Candidate Registration	159	1.200	191	0.29	55
Kidney Paired Donation Donor Registration	159	1.560	248	1.08	268
Kidney Paired Donation Match Offer Management	159	1.520	242	0.67	162
Disease Transmission Event	308	1.810	557	0.62	345
Living Donor Event	251	0.155	39	0.56	22
Safety Situation	449	0.600	269	0.56	151
Potential Disease Transmission	57	8.720	497	1.27	631
Request to Unlock Form	449	42.399	19,037	0.02	381
Initial Donor Registration	57	335.720	19,136	3.00	57,408
OPO Notification Limit Administration	57	0.490	28	0.17	5
Potential Transplant Recipient	308	4718.480	1,453,292	0.05	72,665
Death Notification Registration	57	185.770	10,589	0.42	4,447
Deceased Donor Death Referral	57	53.840	3,069	0.50	1,535

Donor Hospital Registration	57	0.040	2	0.08	0
Donor Organ Disposition	57	335.720	19,136	0.17	3,253
Transplant Center Contact Management	251	637.500	160,013	0.06	9,601
Total = 70 forms	9,146		2,352,736		643,929

* The numbers of respondents and the numbers of total responses in the burden table were updated with 2021 OPTN data and reflect increases in the number of organ transplants and changes in the number of respondents (Transplant Hospitals, OPO, and Histocompatibility Labs).

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's and the OPTN's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

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[FR Doc. 2022-21119 Filed: 9/28/2022 8:45 am; Publication Date: 9/29/2022]